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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

60 8th Street, N.E.
Atlanta, Georgia 30309

March 3, 2005

VIA FEDERAL EXPRESS

George E. Earp, Owner/Partner
David E. Earp, Owner/Partner
Earp's Wholesale Seafood
310 Maywood Avenue
Raleigh, NC 27603-2308

Warning Letter
05-ATL-09

Dear Messrs. Earp:

On January 12 - 13, 2005, FDA conducted an inspection of your seafood processing facility located at 310 Maywood Ave., Raleigh, North Carolina. During that inspection, our investigator documented serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section whenever a HACCP plan is necessary, or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 342(a)(4). Accordingly, your fresh, histamine-forming fish are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov*.

The deviations of concern are as follows:

1) You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish or fishery product that you process, to comply with 21 CFR 123.6(a). You also must have and implement a HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Among other items, the HACCP plan must, at a minimum, list the critical control points ("CCPs") for each of the identified food safety hazards, to comply with 21 CFR 123.6(c). A CCP is defined in 21 CFR 123.3(b) as "a point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be

prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for fresh histamine-forming fish does not list the critical control points of "Receiving," "Cooler Storage," and "Shipping" for controlling the food safety hazard of histamine formation. You need to redo your HACCP plan so that each CCP is listed together with the hazard(s) that need to be controlled and accompanied by proper monitoring procedures/frequencies, a record keeping system, and verification procedures that will enable you to determine if the listed critical limit has been exceeded, and whether corrective action needs to be taken. We are enclosing a copy of *Chapter 7: Scombrotoxin (Histamine) Formation* from the third edition of the Fish & Fisheries Products Hazards & Controls Guidance for your use in developing an adequate HACCP plan for histamine-forming fish.

2) You must have a HACCP plan that, at a minimum, lists the critical limits that must be met at each of the critical control points, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for fresh histamine-forming fish lists a critical limit, i.e., "COOLER TEMPERATURE NOT TO EXCEED [redacted] DEGREES" that is not adequate to control the histamine formation hazard. You should refer to Chapter 7 of the third edition of the Fish & Fisheries Products Hazards & Controls Guidance for information relating to the adequate cooler storage temperature for histamine-forming fish.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may recommend that the United States bring a legal action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as copies of HACCP plans and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Mary Woleske

Mary H. Woleske, Director
Atlanta District

Enclosure